K110911

SECTION 7 - SUMMARY OF SAFETY AND EFFECTIVENESS

APR 28 2011

(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name & Address
Mazor Robotics Ltd.
7 HaEshel Str.
P.O.B. 3104
Southern Caesarea Industrial Park, 38900
ISRAEL

Official Correspondent
Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as St.
Kfar Saba 44425
Israel

2. Date Prepare: March 2011

3. Device Name

Proprietary Name:	Renaissance System
Common / Usual Name:	Combination of: 1. Spinal Stereotaxic instrument; and 2. 3-D Reconstruction Tool for Mobile X-Ray Devices
FDA Classification Name:	1. 21 CFR 882.4560; Stereotaxic instrument 2. 21 CFR 892.2050; System, image Processing, Radiological
FDA Classification:	Class II, Product Code HAW and LLZ

4. Predicate Devices

The Renaissance System is substantially equivalent to the following device:

Manufacturer	Device	510(k)	Date Cleared
Mazor Robotics	TenZing	K102130	08/26/2010

5. Device Description

The Renaissance system is a device modification of the TenZing system (K102130), which is comprised of the original SpineAssist System and the C-InSight System.

The SpineAssist application enables the surgeon to precisely position surgical instruments or implants during general spinal surgery. This is achieved through pre-operation planning and virtual placement of the surgical instrument or implant (e.g., a screw) based on the patients' CT data. During the surgical procedure the pre-planned instrument or implant positions are located and projected on Fluoroscopy images relative to the SpineAssist device position while the SpineAssist arm is then guided to the actual position. The SpineAssist is described in previously cleared 510(k) submissions K033413, K051676, K063607 and K073467.

The C-InSight application is a software based product, which converts a sequence of two-dimensional fluoroscopy images into a 3D volumetric image, intraoperatively. The C-InSight computer is connected to a traditional C-Arm in the operating room and grabs all images from the C-Arm. Using a tracking algorithm, the C-InSight software is able to convert a continuous scan around the region of interest into a 3D image, intra-operatively. The C-InSight is described in the previously cleared 510(k) submission K081672.

The TenZing System cleared in 510(k) submission K102130 is a workstation which contains both the C-InSight and SpineAssist components in one workstation. This allows the physician to perform SpineAssist procedures and C-InSight procedures as independent applications, but using the same workstation console. Furthermore, the TenZing System allows the surgeon to perform SpineAssist procedures and obtain an intra-operative 3D verification image using the C-InSight application. Thus, the surgeon can obtain real time feedback regarding instrument and/or implant positioning.

The modified system is called the Renaissance System. The device modifications include a newly designed workstation (hardware change), a slightly modified SpineAssist Guiding Device (with colored LED lights), and modified software with improved GUI for the original TenZing software (software change) and the ability to perform CT-Fluoroscopy registration using the fluoroscopy images obtained from the C-InSight application (i.e., CT to C-InSight registration).

6. Intended Use / Indications

The Renaissance System is indicated for precise positioning of surgical instruments or implants during general spinal surgery. It may be used in either open or percutaneous procedures.

Renaissance 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

7. Performance Standards

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the Renaissance device.

8. Performance Testing

The following Performance tests were performed on the Renaissance System:

- Software validation testing in accordance with the FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (January 11, 2002).
- CT to C-InSight Registration Accuracy Testing
- IEC 60601-1 Electrical and Mechanical Safety Testing
- IEC 60601-1-2 Electromagnetic Compatibility Testing

9. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the Renaissance device are substantially equivalent to the predicate device cited above.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mazor Robotics, Ltd.
% Ms. Ahava Stein
Official Correspondent
Regulatory Affairs Consulting
20 Hata'as St., Kfar Saba, 44425
ISRAEL

APR 2 8 2011

Re: K110911
Trade/Device Name: Renaissance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW and LLZ
Dated: March 27, 2011
Received: March 31, 2011

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 1 - INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: Renaissance System

Intended Use Statement:

The Renaissance System is indicated for precise positioning of surgical instruments or implants during general spinal surgery. It may be used in either open or percutaneous procedures.

Renaissance 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

Prescription Use __√__ OR Over-The-Counter Use___

(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110911